DETAILED ACTION

Status of Claims

1.   This action is in reply to the application filed on 12/08/2003, and subsequent preliminary amendment filed on 10/15/2009.

2.   Claims 1-3 and 6-16 have been amended.

3.   Claims 1-16 remain pending.

Response to Arguments

4.   Applicant's arguments have been fully considered, but are now moot in view of the new grounds of rejection. The Examiner has entered a new rejection under 35 USC § 103(a), applied new art and art already of record.

Claim Rejections - 35 USC § 103

5.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6.   The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1.   Determining the scope and contents of the prior art.
   2.   Ascertaining the differences between the prior art and the claims at issue.
   3.   Resolving the level of ordinary skill in the pertinent art.
   4.   Considering objective evidence present in the application indicating obviousness or
           nonobviousness.

7.   Claims 1, 3-11, 21 and 22 are rejected under 35 U.S.C. 103(a) as being

unpatentable over McIlroy (US 5,583,758 A) in view of Smith (US 2007/0214002

A1).

8.   **Claim 1:**

McIlroy, as shown below, discloses the following limitations:

   • *a data processor for identifying a potential change in use of a particular
     treatment by* (see at least Fig. 1, column 4, lines 50-60, column 6, lines 1-9).

   • *examining data representing a plurality of orders generated by healthcare
     clinicians over a particular time period and used in treating a plurality of
     patients, to identify a number of orders initiating application of a particular
     treatment to individual patients of said plurality of patients to address a
     particular medical condition* (see at least Abstract, Fig. 26, column 18, lines
     33-58). In the first citation, physicians and others in the healthcare field who
     utilize the system serve as healthcare clinicians.

Smith further discloses the following limitations:

   • *determining at least one of; (a) whether said number of orders exceeds a
     predetermined threshold and (b) whether a rate of change in said number of
     orders relative to a previously determined number of orders is significant to*

identify a potential change in use of said particular treatment (see at least ¶0121; Claim 17 & 25).

- *a message processor for automatically and proactively initiating generation of a message to alert a message recipient to permit review and potential modification at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment in response determining that at least one of (a) said number of orders exceeds a predetermined threshold, and (b) said rate of change in said number of orders relative to a previously determined number of orders is significant* (see at least ¶0121; Claim 17 & 25).

Here, the chronic health related condition is set with predetermined intervention guidelines, when thresholds are reached; the nurse case manager is notified with an alert message. Also, performing the outpatient treatment serves as administering orders. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of McIlroy so as to have include administering treatment with the predetermined thresholds of Smith to provide a more comprehensive risk reducing treatment plan to have improved the overall efficiency, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

9. **Claim 2:**

McIlroy, as shown below, discloses the following limitation:

- an acquisition processor for acquiring data representing said plurality of orders used in treating said plurality of patients and for associating an individual order with at least one of, a) said particular medical condition and

(b) a set of medical conditions including said particular medical condition (see at least Fig. 1, Fig. 10, Fig. 11, Fig. 12a, column 11, lines 6-34).

McIlroy's CPU serves as a data processor in figure 1. Here, medical

categories are medical conditions of a patient and they are collected using

McIlroy's computer program. Also, orders and plurality of orders are represented

by diagnosis codes, which are pointed out in figure 12a.

10.   **Claim 3:**

McIlroy, as shown below, discloses the following limitation:

- an acquisition processor for acquiring data identifying a plurality of medical conditions exhibited by an individual patient and for applying said data identifying said plurality of medical conditions exhibited by said individual patient in associating said individual order with said at least one of, (a) said particular medical condition and (b) a set of medical conditions including said particular medical condition (see at least Fig. 10, Fig. 11, column 11, lines 6-18).

Again, McIlroy's processor has the ability to collectively acquire medical

conditions for medical patients.

11.   **Claim 4:**

McIlroy, as shown below, discloses the following limitation:

- wherein said acquisition processor derives data identifying said plurality of medical conditions and potentially associated sub-conditions, wherein a potentially associated sub-condition of a medical condition is identified using a clinical knowledge model that associates medical conditions based upon one of potential etiology, potential complication, clinical associations, and a

combination thereof (see at least Fig. 9a, column 9, line 5 to column 10, line 23).

McIlroy's chart outlining the guideline development process serves as the

clinical knowledge model that considers a multitude of scientific support.

12. **Claim 5:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data identifying said plurality of medical conditions exhibited by said individual patient is acquired from a stored patient record (see at least Fig. 9b, Fig. 10, Fig. 11, column.

Figure 9b shows the process to entering a patient's medical record, while the

plurality of medical conditions are stored and displayed in figures 10 and 11.

13. **Claim 6:**

McIlroy, as shown below, discloses the following limitation:

- wherein said potential change in use of said particular treatment comprises at least one of, (a) a change in frequency of use of said particular treatment by physicians to treat said particular medical condition and (b) a change in type of medical condition treated with said particular treatment (see at least Fig. 16, Fig. 24B, column 18, lines 12-15).

In both figures, McIlroy's care change option serve as a change in medical

condition treatments.

14. **Claim 7:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data processor correlates data representing a particular order of said plurality of orders with at least one of, (a) said particular medical condition, (b) another order of said plurality of orders and (c) a documentation template used for initiating an order (see at least Fig. 15, column 12, lines 36-47).

Figure 15 serves a software documentation template that has the option to correlated collected medical treatment case information.

15. **Claim 8:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data processor performs said correlation using at least one of, (i) cluster analysis, 25 (ii) best fit analysis and (iii) a statistical correlation technique (see at least column 7, lines 35-40).

Here, the clinical decision data collection component is used to perform statistical correlation techniques.

16. **Claim 9:**

McIlroy, as shown below, discloses the following limitation:

- wherein said message processor initiates generation of a message prompting a user with a suggestion of at least one of, (a) an additional order item to be added to an existing order set documentation template and (b) a deletion of an order item from an existing order set documentation template (see at least Fig. 15, column 12, lines 36-47).

Figure 15 displays the addition of multiple treatment options. The specialist review screen is the means for messaging and prompting a user.

17.   **Claim 10:**

McIlroy, as shown below, discloses the following limitation:

- wherein a second message is received in response to said message alert and said second message initiates at least one of, (a) an addition of an order item to an existing order set documentation template and (b) a deletion of an order item from an existing order set documentation template (see at least Fig. 15, column 12, lines 36-47, 13, lines 42-47).

    Here, there are two instances where message alerts within this

documentation template.

18.   **Claim 11:**

McIlroy, as shown below, discloses the following limitation:

- wherein an acquisition processor for acquiring data identifying a plurality of medical conditions exhibited by an individual patient and (see at least Fig. 10, Fig. 11, column 11, lines 6-18).

- applying said data identifying said plurality of medical conditions exhibited by said individual patient in associating said individual order with said at least one of, (a) said particular medical condition and (b) a set of medical conditions including said particular medical condition (see at least Fig. 1, Fig. 10, Fig. 11, Fig. 12a, column 11, lines 6-34).

    McIlroy's CPU serves as a data processor in figure 1. Here, medical

categories are medical conditions of a patient and they are collected using

McIlroy's computer program. Also, orders and plurality of orders are represented

by diagnosis codes, which are pointed out in figure 12a.

19.   **Claim 12:**

McIlroy, as shown below, discloses the following limitation:

- wherein said data processor monitors data representing orders to identify said data representing said plurality of orders for examining based on at least one of, (i) a predetermined particular order item in an order set, (ii) a predetermined particular order documentation template, (iii) a source of a predetermined particular order and (iv) a predetermined particular medical condition likely to be associated with an order (see at least Fig. 10, Fig. 11, column 11, lines 6-18).

Here, McIlroy's predefined medical categories in figures 10 and 11 serve as a

predetermined particular order documentation template.

20.   **Claim 13:**

McIlroy, as shown below, discloses the following limitation:

- *a data processor for identifying a potential change in use of a particular treatment by, examining data representing a plurality of orders generated <u>by healthcare clinicians</u> over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition and* (see at least Abstract, Fig. 26, column 18, lines 33-58).

- *determining whether a change in said number of orders relative to a previously determined number of orders is significant* (see at least column 18, lines 16-25).

Smith further discloses the following limitations:

- *<u>automatically and proactively</u> prompting a user with a suggestion of at least one of; (a) an additional order item to be added to an existing order set documentation template and (b) a deletion of an order item from an existing order set documentation template <u>in response to determining that the change</u>*

in said number of orders relative to the previously determined number of
orders is significant (see at least ¶0121; Claim 17 & 25).

Therefore, it would have been obvious to one of ordinary skill in the art, at the

time of the invention, to have modified the system of McIlroy so as to have

include administering treatment with the predetermined thresholds of Smith to

provide a more comprehensive risk reducing treatment plan to have improved the

overall efficiency, since so doing could be performed readily and easily by any

person of ordinary skill in the art, with neither undue experimentation, nor risk of

unexpected results.

21.   **Claim 14:**

McIlroy, as shown below, discloses the following limitation:

- *an acquisition processor for acquiring data representing said plurality of*
  orders used in treating said plurality of patients and for associating an
  individual order with at least one of (a) said particular medical condition and
  (b) a set of medical conditions including said particular medical condition (see
  at least Fig. 1, Fig. 10, Fig. 11, Fig. 12a, column 11, lines 6-34).

- *a data processor for identifying a potential change in use of a particular*
  treatment by, examining data representing a plurality of orders associated
  with a particular medical condition and generated by healthcare clinicians
  over a particular time period and used in treating a plurality of patients, to
  identify a number of orders initiating application of a particular treatment to
  individual patients of said plurality of patients (see at least Abstract, Fig. 26,
  column 18, lines 33-58).

Smith further discloses the following limitations:

- *determining whether a change in said number of orders relative to a*
  previously determined number of orders is significant to identify a potential

change in use of said particular treatment (see at least ¶0121; Claim 17 & 25
).

* _a message processor for automatically and proactivel7 initiating generation of
a message to alert a message recipient to permit review and potential
modification at least one order for said particular treatment corresponding to
the of-an identified potential change in use of said particular treatment in
response to determining that the change in said number of orders relative to
the previously determined number of orders is significant_ (see at least ¶0121;
Claims 17& 25).

Here, the chronic health related condition is set with predetermined

intervention guidelines, when thresholds are reached; the nurse case manager is

notified with an alert message. Also, performing the outpatient treatment serves

as administering orders. Therefore, it would have been obvious to one of ordinary

skill in the art, at the time of the invention, to have modified the system of McIlroy

so as to have include the message alert of Smith to provide a more

comprehensive risk reducing treatment plan to have improved the overall

efficiency, since so doing could be performed readily and easily by any person of

ordinary skill in the art, with neither undue experimentation, nor risk of

unexpected results.

22.   Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Hendrickson (US 5,740,800 A) in view of Smith (US 2007/0214002 A1).

23.   **Claim 15:**

Hendrickson, as shown below, discloses the following limitation:

- *examining data representing a plurality of orders generated <u>by healthcare clinicians</u> over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition* (see at least Fig. 2-4A, column 2, lines 10-56, column 4, line 55 to column 5, line 20).

Smith further discloses the following limitations:

- *determining at least one of; (a) whether said number of orders exceeds a predetermined threshold and (b) whether a rate of change in said number of orders relative to a previously determined number of orders is statistically significant <u>to identify a potential change in use of said particular treatment</u>* (see at least ¶0121; Claims 17 & 25).

- *<u>automatically and proactively</u> initiating generation of a message to alert a message recipient <u>to permit review and potential modification at least one order for said particular treatment corresponding to the</u> identified potential change in use of said particular treatment <u>in response determining that at least one of (a) said number of orders exceeds a predetermined threshold, and (b) said rate of change in said number of orders relative to a previously determined number of orders is significant</u>* (see at least ¶0121; Claims 17 & 25).

Here, the chronic health related condition is set with predetermined intervention guidelines, when thresholds are reached; the nurse case manager is notified with an alert message. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of Hendrickson so as to have include the message alert with the predetermined thresholds of Smith to provide a more comprehensive risk reducing treatment plan to have improved the overall efficiency, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

24.   **Claim 16:**

Hendrickson, as shown below, discloses the following limitation:

- *acquiring data representing said plurality of orders used in treating said plurality of patients and for associating an individual order with at least one of (a) said particular medical condition, and (b) a set of medical conditions including said particular medical condition* (see at least Fig. 2-4A, column 2, lines 10-56, column 4, line 55 to column 5, line 20).

Response to Arguments

25.   Applicant' arguments with respect to claims 1-16 have been fully considered but are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed 10/15/09.

26.   (1) Applicant argues on the basis that the McIlroy reference does not teach *"generated by healthcare clinicians," and a "number of orders" are analyzed for a "determination" related to "changed significance"*. Rather, Hendrickson's method has clinical pathway software used by healthcare clinicians to analyze different predefined order sets as it relates to a significant time change.

27.   (2) Applicant argues on the basis that the McIlroy reference does not teach *"an alert message" or "suggestion" is "automatically and proactively", "initiated" or "prompted" to "permit review and potential modification at least one order for said particular treatment."* Rather, Smith's system automatically sends an alerts

message to a physician or nurse, when the predetermined thresholds are

exceeded.

Conclusion

The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

Applicant's amendment necessitated any new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Teresa Woods** whose telephone number is **571.270.5509.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

***Commissioner of Patents and Trademarks*
Washington, D.C. 20231**

or faxed to **(571) 273-8300**.

Hand delivered responses should be brought to the **United States Patent**

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